OIG Issues Unfavorable Advisory Opinion on Common Arrangements between Physician Practices and Health Care Providers

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On August 15, 2023, the Office of Inspector General for the Department of Health and Human Services (OIG) issued a negative <u>Advisory Opinion</u> regarding a turnkey physician-owned entity (Newco) operated by an existing provider of intraoperative neuromonitoring (IONM) services (Company). In reaching its determination, the OIG stated that Newco and its arrangements with the IONM Company (Proposed Arrangement) would present a significant risk under the federal Anti-Kickback Statute (AKS) primarily because it exhibits many indicia of a suspect contractual joint venture.

Proposed Arrangement

IONM services entail both a technical component and a professional component. Presently, the Company contracts with hospitals and ambulatory surgery centers to perform the technical component of the IONM services and arranges for the professional component of the IONM services to be performed by neurologists employed or engaged by a physician practice (Practice) managed by the Company.

Under the Proposed Arrangement, the Company would form and operate Newco, which would be wholly owned by surgeons, to perform the technical component of the IONM services. The Company would provide day-to-day management services to Newco, and Newco would engage the Practice to perform the IONM professional services through its neurologists. Newco would bill third party payors for both components of the IONM services.

The Company estimated that Newco would achieve substantial profits (i.e., the difference in fees paid to the Company and the Practice and Newco's reimbursement from third-party payors) and that the Company's profits would substantially decrease as compared to its current business model. But the Company certified that it is considering the Proposed Arrangement for competitive reasons because its referring surgeons are frequently approached by competitors offering similar arrangements, and thus the Proposed Arrangement is necessary to avoid losing business.

Under the Proposed Arrangement, the surgeon owners of Newco would refer their own patients to Newco for IONM services. The Company would attempt to ensure that the surgeon owners did not refer Medicare and Medicaid patients to Newco, but it would not be able to enforce any such restrictions because Newco would be responsible for billing third party payors. Moreover, if the surgeon owners do not refer Medicare and Medicaid beneficiaries to Newco, they likely would refer these patients to the Company for the technical component and to the Practice for the professional services.

Analysis

Citing its <u>2003 Special Advisory Bulletin on Contractual Joint Ventures</u>, the OIG determined that the Proposed Arrangement presents significant risk under the AKS because it could be used as a vehicle to induce referrals of Medicare and Medicaid business from the surgeon owners to Newco as well as to the Company and the Practice. According to the OIG, the Proposed Arrangement has the following characteristics of a suspect joint venture:

- Little Financial Risk. The surgeon owners' actual financial and business risk would be minimal because they would control or influence the amount of business they would direct to Newco.
- New Line of Business Dependent on Referrals. The surgeon owners would be expanding into a related line of business – IONM services – that would be dependent on the surgeon owners' referrals.
- Established Provider of the Services. The Company and the Practice already offer the same services that Newco would provide and would compete with Newco absent the Proposed Arrangement
- Share in the Profits. The Company and the Practice would be effectively agreeing to forgo a portion of the profits they would have realized if they continued to provide the IONM services directly. The Proposed Arrangement would provide the surgeon owners the opportunity to share in the profits. The OIG further observed that the Proposed Arrangement would create financial incentives that could corrupt the surgeon owners' medical decision-making and result in overutilization or inappropriate utilization of IONM services and improper steering to Newco.
- Scope of Services Provided by the Manager. The surgeon owners would not participate in the operation of Newco and instead would contract out substantially all of Newco's operations to the Company.

This Advisory Opinion is yet another example of OIG guidance reiterating its view that joint ventures formed between entities that provide health care items or services and entities that refer business can present risk under the AKS. In addition to this Advisory Opinion and the Special Advisory Bulletin on Contractual Joint Ventures, the OIG has issued multiple Advisory Opinions on such joint ventures. Most recently, the OIG issued a <u>negative Advisory Opinion</u> on a proposed contractual joint venture for therapy services between an existing therapy services provider and an owner of long-term care facilities.

Characteristics of Contractual Joint Ventures that Present Minimal Risk of Fraud and Abuse

In contrast, the OIG issued a <u>favorable Advisory Opinion</u> on a contractual joint venture between a sleep testing provider and a hospital in 2010. Under the contractual joint venture, the sleep testing

provider contracted with the hospital to provide marketing and education services, equipment, technology, supplies, and staff necessary to operate a sleep testing facility in the hospital's space. In addition to providing space, the hospital would provide certain equipment, a medical director, and certain administrative services. The hospital would bill for the sleep testing services as services provided by the hospital "under arrangements." The sleep testing provider would collect from the hospital fixed, annual fees for its services. The OIG distinguished the arrangement from suspect joint ventures based on the following factors:

- No Financial Incentives for Referring Physicians. Unlike the surgeons ordering IONM services in the 2023 Advisory Opinion, the physicians ordering and interpreting sleep testing services do not share in the profits earned through the contractual joint venture, and there are no financial incentives to the physicians that might corrupt their medical decision-making.
- Financial Risk Assumed by the Hospital which also Provides a Substantial Amount of the Services. The OIG noted that the arrangement is readily distinguishable from a turnkey arrangement where one provider supplies a captive stream of referrals, while another provider which is already an established provider of the services furnishes the bulk of the contractual joint venture's operations. The hospital would assume business risk and contribute substantially to furnishing the sleep testing services for which it bills, including providing space, equipment, a medical director, and administrative services.
- Fixed Fees that Do Not Take Into Account Referrals. The fees charged to the hospital by the sleep testing provider for equipment, marketing, and other services would be set in advance and remain constant regardless of the number of patients receiving services or whether the hospital collects payment for the services. Thus, the fees would not build in a reimbursement guarantee for the Hospital by immunizing it against failure to collect payment.

Health care entities seeking to form a similar joint venture should proceed with caution and avoid structuring a joint venture that exhibits the characteristics identified by the OIG as potentially indicative of a prohibited joint venture arrangement.

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